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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/524,168

09/30/2005

Peter Terness

4121-176

2833

7590

04/19/2007

Steven J Hultquist  
Intellectual Property/Technology Law  
P O Box 14329  
Research Triangle Park, NC 27709

EXAMINER

SANG, HONG

ART UNIT

PAPER NUMBER

1643

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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31 DAYS

04/19/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/524,168

Applicant(s)

TERNESS ET AL.

Examiner

Hong Sang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 September 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21, 23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-21 and 23-24 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

**RE: Terness et al.**

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- Group I, claim(s) 1-6, and 8-10, drawn to a surface glycoprotein.
- Group II, claim 7, drawn to a method of making the surface glycoprotein.
- Group III, claim(s) 11-15, drawn to a nucleic acid molecule encoding a surface glycoprotein ACA, an expression vector comprising the nucleic acid molecule, a host cell transformed with the expression vector.
- Group IV, claim 16, a process for producing a surface glycoprotein ACA comprising culturing a transformed host cell.
- Group V, claim(s) 17-18, and 24, drawn to an antibody to a surface glycoprotein.
- Group VI, claim 19, 20 and 23, drawn to a method for the diagnosis of a tumor associated with overexpression of ACA or a predisposition for such a tumor using an antibody.
- Group VII, claim(s) 21, drawn in part to a pharmaceutical composition containing a compound capable of reducing or eliminating the expression of the nucleic acid sequence encoding the surface glycoprotein ACA.
- Group VIII, claim(s) 21, drawn in part to a pharmaceutical composition containing a compound capable of reducing or eliminating the biological activity of ACA.

2. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or

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corresponding special technical features for the following reasons: the special technical feature linking the Groups I-VIII appears to be the surface glycoprotein comprising the following features: a) it is GPI-anchored on the cell surface; b) it can be removed from the cell membrane by treatment with PI-PLC; and c) its GPI-anchor is characterized by a non-acetylated inositol ring and diacyl glycerol as lipid tail of the anchor (see claim 1).

The surface glycoprotein of claim 1 cannot be a special technical feature under PCT Rule 13.2 because it is shown in the prior art. US 5,519,120 (Date of Patent:

5/21/1996) teaches a GPI-anchored protein  $\mu$ -PAR which can be removed from the cell surface by treatment with PI-PLC (see columns 55-56). US 5,519,120 teaches that the majority of the GPI-anchored proteins are susceptible to PI-PLC, which releases the proteins into the medium by removing the diacylglycerol portion of the glycolipid (see column 55, lines 54-60). Because  $\mu$ -PAR can be removed by the treatment of PI-PLC, its GPI-anchor would have a non-acetylated inositol ring as evidenced by Chen et al. (PNAS 1998, 95: 9512-9517, IDS). Chen et al. teach that the PI-PLC resistance of a GPI-anchored protein is due to acetylation of an inositol hydroxyl group (see page 9512, left column, last paragraph). Moreover, US 5,519,120 teaches treating cells with PI-PLC (see column 55-56), the proteins, which are released into the medium by PI-PLC treatment, include all the GPI-anchored proteins that are present on the cell surface. Such GPI-anchored proteins would include those that are characterized by a non-acetylated inositol ring and diacyl glycerol as lipid tail of the anchor. Therefore the technical feature linking the inventions is not novel and does not provide contribution

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over the prior art. As such, unity of invention is lacking and the inventions are deemed to be separate.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

- a): SEQ ID NO.1, SEQ ID NO.2, SEQ ID NO.3, SEQ ID NO.4, SEQ ID NO.5, SEQ ID NO.6, SEQ ID NO.7, SEQ ID NO.8, SEQ ID NO.9, SEQ ID NO.10, and SEQ ID NO.11.
- b): melanoma, leukemia, renal cancer, lung cancer, breast cancer, colon cancer, gastric cancer, or any other form of cancer.

The claims are deemed to correspond to the species listed above in the following manner:

- a): claims 5 and 11
- b): claim 23.

The following claim(s) are generic: 1-4, 6-10, 12-19, 20 and 24.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the reasons set forth above (see paragraph 2).

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

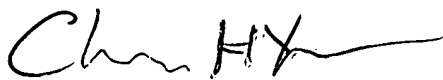
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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hong Sang, Ph.D.  
Art Unit 1643  
April 10, 2007



CHRISTOPHER H. YAEN  
PRIMARY EXAMINER